

We claim:

5 1. A metered dose Inhaler having part or all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising beclomethasone dipropionate or a physiologically acceptable solvate thereof, and a fluorocarbon propellant, optionally in combination with one or more other pharmacologically active agents or one or more excipients.

10 2. An inhaler according to Claim 1 containing said drug formulation.

3. An inhaler according to Claim 2 wherein said drug formulation further comprises a surfactant.

15 4. An inhaler according to Claim 2 or Claim 3 wherein said drug formulation further comprises a polar cosolvent.

5. An inhaler according to claim 2 wherein said drug formulation comprises 0.01 to 5 % w/w based on the weight of propellant of a polar cosolvent, which formulation is substantially free of surfactant.

20 6. An inhaler according to Claim 4 or Claim 5, wherein the polar cosolvent is ethanol.

25 7. An inhaler according to any one of Claims 2 to 6, wherein said drug formulation comprises beclomethasone dipropionate or a physiologically acceptable solvate thereof in combination with salmeterol or salbutamol or a physiologically acceptable salt thereof.

30 8. An inhaler according to Claim 2, wherein said drug formulation comprises
(a) beclomethasone dipropionate monohydrate, the particle size of substantially all the monohydrate being less than 20 microns;
(b) at least 0.15% by weight of the formulation of water in addition to the water of crystallisation associated with the monohydrate; and

(c) a fluorocarbon propellant.

9. An inhaler according to Claim 8, wherein the formulation further comprises 0.05 to 3% w/w based on the propellant of a polar cosolvent.

5 10. An inhaler according to Claim 9, wherein the polar cosolvent is ethanol.

10 11. An inhaler according to Claim 2, wherein said drug formulation consists essentially of beclomethasone dipropionate or a physiologically acceptable solvate thereof, optionally in combination with one or more other pharmacologically active agents, a fluorocarbon propellant and 0.01 to 5 % w/w based on the propellant of a polar cosolvent, which formulation is substantially free of surfactant.

15 12. An inhaler according to any one of Claims 2 to 11, wherein the fluorocarbon propellant is 1,1,1,2-tetrafluoroethane or 1,1,1,2,3,3,3-heptafluoro-n-propane or mixtures thereof.

20 13. An inhaler according to Claim 12, wherein the fluorocarbon propellant is 1,1,1,2-tetrafluoroethane.

14. An inhaler according to any one of claims 1 to 13 comprising a can made of metal wherein part or all of the internal metallic surfaces are coated.

25 15. An inhaler according to Claim 14 wherein the metal is aluminium or an alloy thereof.

16. An inhaler according to any one of Claims 1 to 15, wherein said fluorocarbon polymer is a perfluorocarbon polymer.

30 17. An inhaler according to Claim 16 wherein said fluorocarbon polymer is selected from PTFE, PFA, FEP and mixtures thereof.

18. An inhaler according to any one of Claims 1 to 17, wherein said fluorocarbon polymer is in combination with a non-fluorocarbon polymer selected from polyamideimide and polyethersulphone.

5 19. An inhaler according to any one of Claims 1 to 18 comprising a substantially ellipsoidal base.

20. A metered dose inhaler system comprising a metered dose inhaler according to any one of Claim 1 to 19 fitted into suitable channelling device for 10 oral or nasal inhalation of the drug formulation.

10 21. Use of a metered dose inhaler system according to Claim 20 for the treatment of respiratory disorders.

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